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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,184	07/16/2003	Eckhard Alt	P0028935.05/LG10126	2237
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MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MINNEAPOLIS, MN 55432-9924			EXAMINER SZMAL, BRIAN SCOTT	
			ART UNIT 3736	PAPER NUMBER
			NOTIFICATION DATE 01/19/2011	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/622,184

Applicant(s)

ALT, ECKHARD

Examiner

Brian Szmaj

Art Unit

3736

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31 and 33-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31 and 33-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 August 2010 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-945)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Drawings

1. The drawings were received on August 25, 2010. These drawings are acceptable.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 31 and 33-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Riff (5,876,353).

Riff discloses an impedance monitor for discerning edema through evaluation of the respiratory rate and further discloses measuring local impedance of a portion of a patient's body generally occupied by the lungs solely through surface mounted electrodes (15a,15b) on the device with the device implanted subcutaneously in the patient's body (Figure 1); determining when the local impedance measurements are indicative of a condition of congestive heart failure based on factors other than the existence of edema (Column 13, lines 59-65); detecting the patient's heart rate or activity pattern through the electrodes while concurrently monitoring the local impedance measurement to evaluate cardiopulmonary status of the patient (Column 5, lines 32-36 and 39-42); evaluating the trend of the heart rate/activity pattern and the concurrent local impedance measurements against one another over a selected period

of time, as an additional indicia of congestive heart failure (Column 5, lines 32-36; Column 17, lines 20-23); and determining a trend based on the impedance value and the characteristic of the heart, the trend being indicative of a condition of congestive heart failure (Column 5, lines 32-36; Column 17, lines 20-23).

4. Claims 31 and 33-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Combs et al (5,957,861).

Combs et al disclose an impedance monitor for discerning edema through evaluation of the respiratory rate and further disclose measuring local impedance of a portion of a patient's body generally occupied by the lungs solely through surface mounted electrodes (15a,15b) on the device with the device implanted subcutaneously in the patient's body (Figure 1); determining when the local impedance measurements are indicative of a condition of congestive heart failure based on factors other than the existence of edema (Column 13, lines 59-65); detecting the patient's heart rate or activity pattern through the electrodes while concurrently monitoring the local impedance measurement to evaluate cardiopulmonary status of the patient (Column 5, lines 32-36 and 39-42); evaluating the trend of the heart rate/activity pattern and the concurrent local impedance measurements against one another over a selected period of time, as an additional indicia of congestive heart failure (Column 5, lines 32-36; Column 17, lines 20-23); and determining a trend based on the impedance value and the characteristic of the heart, the trend being indicative of a condition of congestive heart failure (Column 5, lines 32-36; Column 17, lines 20-23).

Response to Arguments

5. Applicant's arguments filed August 25, 2010 have been fully considered but they are not persuasive.

The Applicant argues the prior art of Riff does not show, disclose or suggest means for determining congestive heart failure on the basis of factors other than the existence of edema, And also does not show, disclose or suggest detecting the patient's heart rate/activity pattern and evaluating a trend of the pattern and lung impedance measurements against one another over a selected period of time as an indicia of congestive heart failure. The Examiner respectfully disagrees. Riff discloses in Column 13, lines 9-26 disclose the measurement of heart rate and the combination of the edema measurements with the measured heart rate to provide an enhanced diagnosis. Furthermore, with regards to Figure 11 and the written description of Figure 11 at Column 16, lines 61-67 and Column 17, lines 1-23, Riff discloses the use of the respiratory rate that is compared to the impedance measurement, and also includes other physiological indicators of edema for the comparison. For one of ordinary skill in the art, the respiratory rate can be correlated to the heart rate/activity of the patient, since an increased respiration can be caused by an increased heart rate, or can be caused by a low heart rate.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the surface mounted electrodes perform both the measurement of the impedance and the measurement of the heart rate) are not recited in the rejected claim(s).

Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The current claim language can be reasonably interpreted as separate surface mounted electrodes for both the measurement of the impedance and the heart rate, such that there are a plurality of surface mounted electrodes that are designed to measure impedance and electrodes that are designed to measure the heart rate of the patient.

With regards to the Applicant's arguments to the use of a single set of surface mounted electrodes that measure both the impedance and heart rate not being a simple concept, the Examiner would like to respectfully point out the current specification fails to sufficiently disclose how the electrodes for measuring impedance can also be used to measure the heart rate at the same time (concurrently). For instance, based on Figure 3, electrodes 10, 12, 14 and 16 are connected only to the impedance generator, and the current specification does not disclose how the impedance generator can both determine the impedance of the tissue using electrodes 10, 12, 14 and 16, as well as the heart rate of the patient using electrodes 14 and 16, at the same time. At best, one of ordinary skill in the art can reasonably use the same electrodes to measure both the impedance and the heart rate, at different times.

Regarding the Applicant's arguments with respect to Combs et al, the Examiner would like to respectfully point out the disclosures of Riff and Combs et al are similar and therefore the above response regarding Riff is also applicable to the prior art of Combs et al.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736